# Exhibit 3

# Chemical Handler's Manual

## A Guide to Chemical Control Regulations

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# A Guide to Chemical Control Regulations

**Karen P. Tandy**
Administrator

**Laura M. Nagel**
Deputy Assistant Administrator

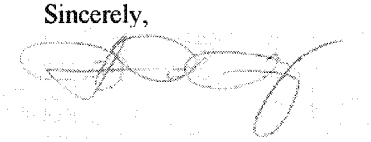
**Patricia M. Good**
Chief, Liaison and Policy Section

# Message from the Administrator

The Drug Enforcement Administration (DEA) is pleased to provide the ***Chemical Handler's Manual*** to assist you in understanding the provisions of the chemical control laws and their implementing regulations. These laws, including the Chemical Diversion and Trafficking Act of 1988, the Domestic Chemical Diversion Control Act of 1993, the Comprehensive Methamphetamine Control Act of 1996, and the Methamphetamine Anti-Proliferation Act (part of the Children's Health Act of 2000) amend the Controlled Substances Act of 1970 (CSA). This manual will answer questions you may have concerning your responsibilities under the Controlled Substances Act and provide you with guidance in complying with its regulations. It is also a resource for industry, law enforcement, regulators, and others interested in chemical control.

Drug abuse damages individuals and families and diminishes the fabric of a community and nation. Drug traffickers, motivated by the desire for profit, are eager to divert chemicals from legitimate commerce to manufacture illicit controlled substances. The chemical control laws and regulations provide a strong and effective deterrence. Your adherence to the law and active support for diversion control make you an important partner in protecting our nation's health and safety.

Sincerely,



Karen P. Tandy
Administrator
Drug Enforcement Administration

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# Application of Federal and State Law

Nothing in this manual shall be construed as authorizing or permitting any person to commit any act which is prohibited under other federal laws or obligations under international treaties, conventions, or protocols or state laws. The policy statements and other information in this guide are for the purpose of explaining the Controlled Substances Act (CSA) and its implementing regulations and should not be construed as permitting any person to commit any act prohibited by federal or state law.

The chemical control program is relatively new and steadily evolving. Regulated persons should check periodically for new provisions. New and proposed rules can be found in the Federal Register, or online (http://www.access.gpo.gov/nara/index.html), or by calling 1-888-293-6498. Printed copies of the complete regulations implementing the CSA (Title 21, Chapter II, Code of Federal Regulations (21 CFR), Part 1300 to end), may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

# The Drug Enforcement Administration

The Drug Enforcement Administration is the federal law enforcement agency charged with the responsibility for combating illicit drug manufacture and distribution, as well as the diversion of licitly produced drugs and chemicals. The DEA was established on July 1, 1973, by Presidential Reorganization Plan No. 2 of 1973. It resulted from the merger of the Bureau of Narcotics and Dangerous Drugs, the Office of Drug Abuse Law Enforcement, the Office of National Narcotics Intelligence, elements of the Bureau of Customs which had drug investigative responsibilities, and those functions of the Office of Science and Technology which were drug enforcement related. The Administration was established to control more effectively narcotic and dangerous drug abuse through enforcement and prevention. In carrying out this mission, the DEA cooperates with other federal agencies, foreign, State, and local governments, private industry, and other organizations.

# Origins of the Laws and Regulations

Most illicitly produced drugs result from processes which require chemicals. Drug traffickers depend on access to a variety of chemicals in all parts of the world.

DEA embarked upon a broad chemical control program in 1989 that was based on the Chemical Diversion and Trafficking Act (CDTA) of 1988. At that time, U.S. companies were the main source for 20,000 metric tons of various chemicals used annually to manufacture cocaine in the Andean countries of South America. Among the principal chemicals used by the cocaine manufacturers are acetone, methyl ethyl ketone, ethyl ether, potassium permanganate, hydrochloric acid, methyl isobutyl ketone, and sulfuric acid. The quantity of these chemicals shipped to South America from the United States declined greatly after the CDTA went into effect.

The CDTA was also effective in reducing the supply of illicit methamphetamine. The number of clandestine laboratories seized in the first three years following the law's implementation reversed the trend of the previous three decades and declined by 61 percent. In addition, injuries attributed to illicitly manufactured controlled substances that were reported through the Drug Abuse Warning Network declined by almost 60 percent between 1989 and 1992.

Maintaining this success requires continuous effort to thwart traffickers' never-ending search for new methods of diversion. This is illustrated by more recent changes in the patterns of diversion:

--When the quantity of U.S. chemicals shipped to cocaine manufacturing areas declined, chemical suppliers from other parts of the world emerged as new sources of supply. The U.S. government then undertook an aggressive international campaign to educate and elicit the support of other nations in establishing chemical controls. Today, there is a broad level of international agreement regarding the actions that must be taken to achieve chemical control. Many nations have passed laws to prevent diversion of chemicals.

--As a result of government controls, ephedrine and other chemicals used to manufacture methamphetamine became more difficult to divert. Traffickers then began using over-the-counter capsules and tablets that contained these ingredients. As chemicals rendered into legitimate medicines purportedly for the commercial market, these products were exempted from the CDTA requirements. The Domestic Chemical Diversion Control Act of 1993 (DCDCA) closed this loophole and required DEA registration for all manufacturers, distributors, importers and exporters of List I chemicals. It also established record keeping and reporting requirements for transactions in single-entity ephedrine products.

--When single-entity ephedrine products became regulated, drug traffickers turned to pseudoephedrine. This was addressed by the Comprehensive Methamphetamine Control Act of 1996 (MCA) which expanded regulatory control of lawfully marketed drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine*.

--The Methamphetamine Anti Proliferation Act of 2000 (part of the Children's Health Act of 2000) addressed continuing diversion from the retail level by constricting the category of retail transactions in pseudoephedrine and phenylpropanolamine drug products by reducing the threshold for such transactions from 24 grams to nine grams of pseudoephedrine or phenylpropanolamine base limited to packages of not more than three grams of base. The Act also increased penalties for chemical diversion and provided for restitution to government for cleanup costs.

Traffickers continue to look for loopholes in the laws and for new methods of illicit manufacture. The government continually monitors the situation. When new patterns of abuse and diversion are identified, the government responds with corrective action, striking a balance which allows the supply of chemicals for legitimate commerce while limiting the availability of chemicals for illicit drug production. DEA recognizes the importance of educating industry on the targets and tactics of the illegal drug trade and partnering with industry on preventing diversion as the best overall approach to defeating drug traffickers.

*Due to concerns regarding harmful side effects that phenylpropanolamine (PPA) can have, the Food and Drug Administration has invoked a voluntary ban on over-the counter phenylpropanolamine products.

# Principal Provisions of the Chemical Diversion Control Laws and Regulations

The chemical control laws and the implementing regulations seek to strike a balance between allowing the chemical handler to pursue legitimate business while limiting the availability of chemicals for illicit drug production. The Chemical Diversion and Trafficking Act of 1988 (CDTA), the Domestic Chemical Diversion Control Act of 1993 (DCDCA), the Comprehensive Methamphetamine Control Act of 1996 (MCA), and the Methamphetamine Anti-Proliferation Act of 2000 (MAPA, part of the Children's Health Act of 2000) are the legislative acts which are the foundation of the government's program to prevent chemical diversion.

The laws and regulations require regulated persons (manufacturers, distributors, importers, and exporters of listed chemicals) to implement measures which prevent diversion by:

- obtaining proof of identity from their customers (21 U.S.C. § 830 (a)(3) and 21 CFR §1310.07)
- maintaining retrievable receipt and distribution records (21 U.S.C. § 830 (a) and 21 CFR Part 1310), and
- reporting to the Drug Enforcement Administration (DEA) any suspicious orders[1] (21 U.S.C. § 830 (b)(1) and 21 CFR §1310.05 (a)(1)).

Manufacturers who distribute or export, distributors, importers, and exporters of List I chemicals are also required to:

- register with DEA (21 U.S.C. § 822 (a)(1) and 21 CFR §1309.21), and
- provide controls and procedures to guard against theft and diversion. (21 U.S.C. § 823 (h) and 21 CFR §1309.71-73).

Regulated persons (importers, exporters, brokers and traders in international transactions and transshippers) are required to notify DEA at least 15 days prior to the date of the transaction (21 U.S.C. § 971 (a) and 21 CFR Part 1313). The notification may be provided to DEA on or before the date of importation or exportation under certain conditions. The conditions are specified in the sections titled "Waiver of 15-Day Advance Notification Requirement" and "Criteria for Waiver of Advance Notification Requirement."

Some manufacturers of List I and List II chemicals are required to report annual production data (21 U.S.C. § 830 (b)(2) and 21 CFR §1310.05 (d)).

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1 Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law.

## Inspection Authority

21 U.S.C. § 822 (f) and 21 CFR § 1316.03

DEA has the authority to enter and conduct an inspection of places, including factories, warehouses, or other establishments and conveyances, where persons registered under the CSA, or exempted from registration under the CSA, or regulated persons may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of controlled substances or listed chemicals or where records relating to those activities are maintained. Inspectors are authorized to:

- enter controlled premises and conduct administrative inspections for the purpose of inspecting, copying, and verifying the correctness of records, reports, or other required documents;
- inspect within reasonable limits and to a reasonable manner equipment, finished and unfinished controlled substances, listed chemicals, and related materials and containers;
- make a physical inventory of all controlled substances and listed chemicals on-hand at the premises
- collect samples of controlled substances or listed chemicals.

## Suspension of Shipments

21 U.S.C. § 971 (c) and 21 CFR § 1313.41

DEA has the authority to suspend shipments of a listed chemical for import or export which are not destined for legitimate medical, scientific, or commercial use. DEA may suspend any importation or exportation of a listed chemical based on evidence that the chemical may be diverted for use in the clandestine manufacture of a controlled substance. When a shipment is suspended, the Administration will issue a suspension notice to the regulated person explaining the circumstances of the suspension.

The regulated person to whom the suspension order applies may request an administrative hearing under the Administrative Procedure Act (5 U.S.C. §551 - 559) to determine the issues involving the suspension of shipment (see 21 CFR §1313.51-1313.57). A request for a hearing must be made within 30 days after receipt of shipment suspension notice.

## Active Voluntary Compliance

The CDTA, the DCDCA, the MCA and MAPA imposed reporting requirements on the chemical industry. However, the involvement of private industry and the public should not be limited to the laws enacted by Congress. The vast majority of industry recognizes and supports the idea that the responsibilities of the chemical industry extend beyond the letter of the law to actively supporting efforts to stop the flood of clandestinely produced drugs which plague our nation. Industry's voluntary support constitutes a powerful resource for protecting the health and safety of our nation. We urge each firm to be vigilant and to become a partner with DEA in combating the diversion of chemicals to illegal drug production.

# Awareness of Diversion Patterns

Manufacturers and distributors of listed chemicals can prevent diversion by being aware of diversion patterns, avoiding suspect transactions, and reporting suspicious activities to authorities.

DEA and state/local authorities throughout the United States have noted a continuous and dramatic trend toward the use of pseudoephedrine and ephedrine combination over-the-counter drug products in the clandestine manufacture of methamphetamine.

Many illicit distributors and retailers of pseudoephedrine and combination ephedrine products purchase these List I chemicals from more than one source. Suppliers should be aware of such practices. Some retailers purchase combination ephedrine products as substitute products for pseudoephedrine and vice versa when these products are not substitutes for each other except for the manufacture of illicit methamphetamine.

Other suspect practices include the following:

- Ordering single entity pseudoephedrine and combination ephedrine products in amounts that can not be marketed for legitimate use.

- Ordering pseudoephedrine on a constant basis throughout the year (legitimate retailers order more during cold and flu season).

- Ordering single entity pseudoephedrine products instead of an array of combination pseudoephedrine and other over-the-counter products.

- Selling pseudoephedrine and combination ephedrine products to numerous distributors or retailers concentrated in one metropolitan area.

- Selling brands that have not been on the market for more than several years or that have little or no advertising.

- Selling single entity pseudoephedrine and combination ephedrine packaged in large quantities, particularly when such products are not in blister packs and are marketed for so called off label uses such as weight loss and alertness aids.

- Selling single entity pseudoephedrine and combination ephedrine products to retail establishments that traditionally do little or no marketing of these products and where consumers normally do not purchase over-the-counter medications.

Chemical handlers can find additional guidance on the DEA diversion control web site at www.DEAdiversion.usdoj.gov>Federal Register Notices>registrant actions.

# Definitions

Complete definitions appear in 21 CFR Part 1300 and 21 U.S.C. § 802.

**Broker and Trader** (in an international transaction)

A *broker and trader* is any individual, corporation, corporate division, partnership, association, or other legal entity which assists in arranging an international transaction in a listed chemical by

- negotiating contracts;
- serving as an agent or intermediary; or
- fulfilling a formal obligation to complete the transaction by bringing together a buyer and seller, a buyer and transporter, or a seller and transporter, or by receiving any form of compensation for so doing.

**Chemical Exporter**

A *chemical exporter* is a regulated person who has the power and responsibility for controlling the sending of a listed chemical out of the United States.

**Chemical Importer**

A *chemical importer* is a regulated person who has the power and responsibility for controlling the bringing in or introduction of a listed chemical into the United States.

**Chemical Mixture**

A *chemical mixture* is a combination of two or more chemical substances, at least one of which is not a listed chemical. Concentration limits have been established (21 CFR 1310.12(c)) for chemical mixtures containing ephedrine, n-methylephedrine, n-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine. (These mixtures are often found as dietary or nutritional supplements.) Mixtures equal to or below the concentration limits are not regulated materials.

**Established Business Relationship with a Foreign Customer**

An *established business relationship with a foreign customer* means that the regulated person has exported a listed chemical at least once within the past six months, or twice within the past twelve months to a foreign manufacturer, distributor, or end user of the chemical that has an established business in the foreign country with a fixed street address. A person or business which functions as a broker or intermediary is not a customer for purposes of this definition. The term also means that the regulated person has provided DEA with specified information in accordance with the waiver of 15-day advance notice requirements. DEA can disqualify the foreign customer for waiver of the advance notification requirement. Written explanation of the reasons will be provided. The regulated person is entitled to a hearing within 45 days after the written request.

**Established Record as an Importer**

*Established record as an importer* means that the regulated person has imported a listed chemical at least once within the past six months, or twice within the past 12 months from a foreign supplier. The term also means that the regulated person has provided DEA with the following information, in accordance with the waiver of the 15-day advance notice requirements:

(a) the name, DEA registration number (where applicable), street address, telephone number, telex number, and, where available, the facsimile number of the regulated person and of each foreign supplier; and

(b) the frequency and number of transactions occurring during the preceding 12-month period.

DEA can disqualify the importer for waiver of the advance notification requirement. Written explanation of the reasons will be provided. The regulated person is entitled to a hearing within 45 days after the written request.

**International Transaction**

*International transaction* is a transaction arranged by a broker or trader located in the United States involving the shipment of a listed chemical across an international border (other than a U. S. border).

**Listed Chemical**

*Listed chemical* is any List I chemical or List II chemical. A listing appears in Appendix A.

**List I Chemical**

*List I chemical* is a chemical that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the CSA and is designated a List I chemical by the DEA Administrator or Congress. Chemicals in List I generally are precursors and have been determined by DEA to require a greater level of control than other listed chemicals. Anthranilic acid, ergotamine, piperidine, and drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine are examples of List I chemicals.

**List II Chemical**

*List II chemical* is a chemical, other than a List I chemical, that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the CSA and is designated a List II chemical by the DEA Administrator or Congress. Chemicals in List II are generally reagents and solvents.

**Readily Retrievable**

*Readily retrievable* means that certain records are kept by automatic data processing systems or other electronic or mechanized record keeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner made visually identifiable apart from other items appearing on the record.

**Registrant**

*Registrant* is a person who distributes, imports, exports, or manufactures for distribution or export any List I chemical and who has been granted a Certificate of Registration by the Administrator of DEA to manufacture for distribution, distribute, import or export List I chemicals. Also included are certain controlled substances registrants who handle List I chemicals.

**Regulated Person**

A *regulated person* is any individual, corporation, partnership, association or other legal entity who manufactures, distributes, imports, or exports a listed chemical, or a tableting machine or encapsulating machine, or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or encapsulating machine.

**Regulated Transaction**

21 U.S.C. §802 (39) and 21 CFR § 1300.02 (b)(28)

A *regulated transaction* is a distribution, receipt, sale, importation, exportation, or international transaction involving shipment of a threshold amount of a listed chemical (including a cumulative threshold amount for multiple transactions), a tableting machine or an encapsulating machine. Distributors of listed chemicals who conduct regulated transactions are subject to pertinent regulatory requirements of reporting, recordkeeping and customer identification.

The following transactions are not regulated:

- normal distribution between agents or employees of a single regulated person, and delivery to a common or contract carrier or to or by a warehouseman for storage, unless the carriage or storage is in connection with the distribution, importation or exportation of a listed chemical to a third party.

- any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act **unless**
  - --the drug contains ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, optical isomers, or salts of optical isomers; or
  - --the Administrator has determined that the drug or group of drugs is being diverted; and
  - --the quantity of listed chemical equals or exceeds the threshold established for that chemical.

- sales by retail distributors of ordinary over-the-counter pseudoephedrine or phenylpropanolamine products, directly to walk-in customers or in face-to-face transactions, in below-threshold quantities in a single transaction to an individual for legitimate medical use. Ordinary over-the-counter pseudoephedrine or phenylpropanolamine products are non-liquids sold in package sizes of not more than 3.0 grams of pseudoephedrine base or 3.0 grams of phenylpropanolamine base and packaged in blister packs, each blister containing not more than two dosage units or where the use of blister packs is technically infeasible, packaged in unit dose packets or pouches and for liquids, sold in package sizes of not more than 3.0 grams of pseudoephedrine base or phenylpropanolamine base.

•sales by retail distributors of other than ordinary over-the-counter pseudoephedrine or phenylpropanolamine drug products of nine grams or less of base in a single transaction, sold in package sizes of not more than three grams of pseudoephedrine base or three grams of phenylpropanolamine base (21 USC 802(39)(A)(iv)(II))

•any transaction in a chemical mixture that the Attorney General has by regulation designated as exempt based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered. Chemical handlers should check the Federal Register for the issuance of a final rule on chemical mixtures and subsequent changes.

• transactions in chemical mixtures containing ephedrine, n-methylephedrine, n-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine that are equal to or below concentration limits specified in 21 CFR 1310.12(c)) (see Appendix B)

• harvested plant material that contains ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and/or pseudoephedrine, that is in its natural state or has been processed in a way that preserves the natural constituents in the ratios that are found in the plant's natural state.

• Additionally, the following transactions have been determined by DEA to be excluded from the definition of regulated transaction (21CFR 1310.08):

(a) domestic and import transactions of hydrochloric and sulfuric acids but not including anhydrous hydrogen chloride

(b) exports, transshipments, and international transactions of hydrochloric (including anhydrous hydrogen chloride) and sulfuric acids, except for exports, transshipments and international transactions to the following countries:

Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, French Guiana, Guyana, Panama, Paraguay, Peru, Suriname, Uruguay, Venezuela

(c) domestic transactions of methyl isobutyl ketone (MIBK)

(d) import transactions of methyl isobutyl ketone (MIBK) destined for the United States

(e) export transactions, international transactions, and import transactions for transshipment or transfer of methyl isobutyl ketone (MIBK) destined for Canada or any country outside of the Western Hemisphere

(f) import and export transactions of iodine

(g) import transactions of anhydrous hydrogen chloride

(h) domestic distribution of anhydrous hydrogen chloride weighing 12,000 pounds (net weight) or more in a single container

(i) domestic distribution of anhydrous hydrogen chloride by pipeline

(j) domestic return shipments of reusable containers from customer to producer containing residual red phosphorus or white phosphorus in isotainers and rail cars with capacities greater than or equal to 2500 gallons (in a single container)

(k) domestic, import, and export distributions of gamma-butyrolactone weighing 4,000 kilograms (net weight) or more in a single container

**Retail Distributor**
(relates only to drug products containing ephedrine, pseudoephedrine and phenylpropanolamine) 21 CFR §1300.02(29)

A *retail distributor* is a grocery store, general merchandise store, drug store, or other merchandise store, or other entity or person whose activities as a distributor relating to drug products containing pseudoephedrine, phenylpropanolamine or ephedrine are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. Sale for personal use means the distribution of below-threshold quantities in a single transaction to an individual for legitimate medical use.

The MCA defines retailer as an entity or person whose activities as a distributor of legal drug products containing listed chemicals are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. Distributors who do not meet the retail definition are subject to the requirements for wholesale distributors.

# Registration

21 U.S.C. § 822, 823
21 CFR Part 1309

## Who Must Register

Every person (unless specifically exempted below) who engages or proposes to engage in any of the following activities is required to register annually with DEA:

- •manufacturing a List I chemical for distribution
- •distribution of a List I chemical
- •importation of a List I chemical
- •exportation of a List I chemical

## Separate Registration for Independent Activities

21 CFR §1309.22

The following groups of activities are independent of each other and each requires a separate registration:

1. Retail distributing of drug products that contain List I chemicals. Sales of chemicals such as hydriodic acid or methylamine are non-retail distributions.

2. Non-retail distributing of List I chemicals;

3. Importing List I chemicals (note that importers are authorized to distribute those List I chemicals which they have imported); and

4. Exporting List I chemicals.

## Separate Registration for Separate Locations

21 CFR § 1309.23

A separate registration is required for each principal place of business where a List I chemical is manufactured for distribution, distributed, imported, or exported.

## Exemptions from Registration Requirement

21 CFR § 1309.24

Exempt from registration are:

- a manufacturer of a List I chemical who uses the chemical solely for internal consumption without subsequent distribution or exportation.

- a person who imports or exports a drug product containing a List I chemical if that person is registered with DEA to engage in the same activity with a controlled substance. Security, record keeping and reporting requirements apply.

- a person who distributes a drug product containing a List I chemical, if that person is registered with DEA to manufacture, distribute, or dispense controlled substances. Activities with drug products containing List I chemicals should remain consistent with controlled substances activities; e.g., a retail pharmacy registrant should engage in retail sales rather than wholesale distributions of regulated drug products. Security, record keeping and reporting requirements apply. Distribution of List I chemicals requires a separate registration.

- retail distributors of ordinary over-the-counter pseudoephedrine, phenylpropanolamine and ephedrine combination drug products.

  Retail distributors whose activities as distributors of over-the-counter drug products and combination ephedrine drug products are limited exclusively to sales for personal use, either directly to walk-in customers or in face-to-face transactions by direct sales. Sale for personal use is the sale of below-threshold quantities in a single transaction to an individual for legitimate medical use.

Any distributions of single-entity ephedrine are subject to the registration requirement.

## Applying for Registration

An application for registration (DEA Form 510), and information regarding current fees and renewal of registration may be obtained by contacting your nearest DEA office, by downloading for printing from the diversion control website,

www.DEAdiversion.usdoj.gov>On-line Forms and Applications

or by writing to:

U.S. Department of Justice
DEA, Chemical Registration/ODRR
P.O. Box 2427
Arlington, VA 22202-2427

# Security

21 U.S.C. § 823 (h) and 21 CFR § 1309.71

Registrants are required to provide effective controls and procedures to guard against theft and diversion of List I chemicals. Historically, distributors have focused on knowledge of the customer and close attention to sales as a means to control diversion. Registrants recently have experienced significant thefts of drug products and bulk material. These chemicals are highly sought on the illicit market. It is important for legitimate handlers to provide extra safeguards for chemicals in their possession. Specific attention should be paid to the following areas:

• A List I chemical should be sealed in a container that will reveal any attempts at tampering. If a chemical cannot be stored in such a sealed container, access to the chemical should be controlled through physical means (i.e., locked in a secure place) or through human or electronic monitoring.

• In a retail setting open to the public, single-entity ephedrine products must be stocked behind a counter where only employees have access.

• The registrant should exercise caution in considering the employment of persons who have been convicted of a felony offense relating to controlled substances or listed chemicals. The registrant should assess the risks involved in employing such persons, including the potential for revocation of registration.

• An employee who has knowledge of diversion by a fellow employee has an obligation to report such information to the employer or a responsible representative of the employer. A failure to report such information will be considered in determining future access to areas with List I chemicals. It is the employer's responsibility to inform employees of this policy.

• Some of the factors that registrants should take into account when planning for security include:

1. the quantity of List I chemicals handled,
2. the location of the premises,
3. the type of building construction and the general characteristics of the building,
4. electronic detection and alarm systems,
5. the extent of unsupervised public access to the facility
6. the adequacy of supervision over employees who have access to List I chemicals,
7. procedures for handling guests, maintenance personnel and non-employee service personnel, and
9. adequacy of systems for monitoring receipt, distribution and disposition of List I chemicals.

Any registrant or applicant desiring to determine whether a proposed system of security controls and procedures is adequate for listed chemicals may submit materials and plans regarding the proposed security controls and procedures either to the local Diversion Group Supervisor or to DEA, Chemical Registration Section/ODR, PO Box 28083, Arlington, VA 22202-2427.

## "Know Your Customer" Policy

**It is fundamental for sound operations that handlers take reasonable measures to identify their customers, understand the normal and expected transactions typically conducted by those customers, and, consequently, identify those transactions conducted by their customers that are suspicious in nature. Regulated persons are encouraged to thoroughly review the chapter in this manual entitled "Awareness of Diversion Patterns" and the Appendices, particularly E-1, E-2, and E-3.**

Some states have restrictions on distribution practices that are more stringent than the federal rules. The extent of compliance with state law is taken into consideration when civil, administrative, or criminal actions are under consideration.

It is required that any regulated person verify that a customer for List I products possesses a valid DEA registration or is exempted from that requirement.

The granting of a DEA registration signals only a proper application, the establishment of the required records system, and the required security system at the time of the on-site inspection by DEA. The registration is not a confirmation of proper ongoing business practices and does not relieve the chemical handler of the responsibility to evaluate such transaction.

## Proof of Identity

21 U.S.C. § 830 (a) (3) and 21 CFR § 1310.07

The CSA requires that a regulated person engaging in a regulated transaction must identify the other party to the transaction. The regulated person must verify the existence and apparent validity of a business entity ordering a listed chemical, tableting or encapsulating machine and must maintain customer files. If the regulated person is unable to establish the identity or legitimacy of a customer, sound practice requires the handler to postpone opening an account with this customer until such information is satisfactorily established. Regulated persons should maintain customer files which may be reviewed for adequacy by DEA during on-site visits.

**For domestic transactions**, this may be accomplished at the time the order is placed by having the other party present documents to verify their identity and registration status if a registrant. Verification of documents may be accomplished through the following sources: telephone directory, local credit bureau, local Chamber of Commerce, or the local Better Business Bureau. DEA registration may be verified by DEA. When transacting business with a new representative of a firm, the regulated person must verify the agency status of the representative.

For cash sales or sales to individuals, the proof of identity must consist of at least the signature of the purchaser, a driver's license and one other form of identification. It is recommended that the second form of identification should corroborate the first and should be valid in its own right. If an individual presents an identification card issued by an appropriate state authority in lieu of a driver's license, such identification is acceptable provided that it contains the individual's name, address, a unique identification number, and the individual's photograph. A record, preferably a photocopy, should be kept of proof of identity information.

For new customers that are not individuals or cash customers, the regulated person must establish the identity of the authorized purchasing agent(s) and have on file that person's signature, electronic password or other identification. Once the authorized identity has been established the agent list may be updated annually rather than on each order.

For electronic orders, the identity of the purchaser shall consist of a computer password, identification number or some other means of identification consistent with electronic orders.

For an export transaction, proof of identity is to be accompanied by a good faith inquiry to verify the existence and validity of the foreign business entity. This can be done by verifying the business telephone listing through international telephone information, checking the firm's listing in international or foreign national chemical or commerce directories or trade publications, confirmation through foreign subsidiaries of the U.S. regulated person, or verification through the commercial attaché of the embassy of the country of destination. Official documents provided by the purchaser may confirm the existence and apparent validity of the business entity.

Any exports to individuals or exports paid in cash are suspect and should be handled as such. For such exports, the regulated person must obtain from the purchaser or independently seek to confirm clear documentation which proves the person is properly identified such as through foreign identity documents, driver's license, passport information and photograph, etc. Any regulated person who fails to adequately prove the identity of the other party to the transaction may be subject to the specific penalties provided for violations of law related to regulated transactions in listed chemicals.

# Record Keeping Requirements

21 U.S.C. § 830 and 21 CFR Part 1310

## Persons Required to Keep Records

Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine must keep a readily retrievable record of the transaction. Distribution records are required if the cumulative amount for multiple transactions to a person within a calendar month exceeds the threshold. Thresholds can be found in Appendix B and Appendix C.

## Contents of Regulated Transaction Records

21 CFR § 1310.06

Each record for a domestic transaction must contain the following information:

1. The name, address, and if required, the DEA registration number of each party to the regulated transaction.

2. The date of the transaction.

3. The name, quantity, and form of packaging of the listed chemical, or description of the tableting machine or encapsulating machine (including make, model and serial number).

4. The method of transfer (company truck, picked up by the customer, etc.).

5. The type of identification used by the purchaser and any unique number of that identification.

## Location and Availability of Records

21 CFR § 1310.04

A record of a regulated transaction is required to be kept at the business location where the transaction occurred. As an alternative, the record can be maintained at a single, central location which has been provided in writing and sent to the Special Agent in Charge of the local DEA Division Office by registered or certified mail (return receipt requested). A regulated person with more than one place of business where a record is required to be kept must devise a record keeping system that detects purchases which are made at multiple locations to circumvent the cumulative threshold requirements.

## Maintenance of Records

21 CFR § 1310.04

A record must be kept for two years from the date of transaction.